

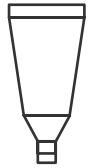


# PHARMACEUTICAL FACTORY



## 1. SYRUP PRODUCTION

Syrups come as solutions, suspensions, and complex dispersion systems that are made in large duplicate containers with powerful mixers, a vacuum system, compressed air, and devices monitoring process parameters with a volume of 500 to 2,000 liters. The produced syrup is then transported to receiving containers/tanks that are connected to the filling and sealing line, which continues into the secondary packaging line. The syrup is filled in glass bottles, sealed with plastic caps, and transported by conveyor belts to the secondary packaging line.



## 2. STEROIDAL AND NON-STEROIDAL OINTMENTS

The production of steroidal and non-steroidal ointments is carried out using two methods, depending on whether they are ointments, creams, or gels.

### OINTMENTS

Ointment production typically involves suspending active and powdered excipients in the prepared base. The base is a mixture of several types of liquid and solid fat components in a certain ratio, obtaining a mass that spreads on the skin easily enough and allowing the active substance to release and act locally.

### CREAMS

Cream production involves the blending of two phases, aqueous and lipid, into a homogeneous structure — commonly in white color — using different types of emulsifiers, which determine the type of resulting emulsion, and in turn the final look of the cream. The active substance can be dissolved in an aqueous or lipid phase depending on its solubility.

### GELS

Gel production involves suspending gelling agents in an aqueous medium, where gelation is achieved by swelling in the basic medium. The active substance is added to the finished gel base dissolved in a suitable solvent or suspended with mixing and vacuuming. The finished gel is transparent or almost white, spreading nicely on the skin and creating a pleasant cooling sensation..

The process of primary packaging of ointments, creams, and gels takes place on a line, by filling the mass into tubes of appropriate volume that are sealed by machine, with batch and expiration date information printed on the tube. The filled, sealed tubes are transported by conveyor belts to the secondary packaging line at the Secondary Packaging Plant.

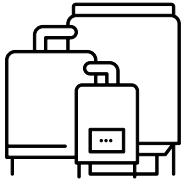
## 3. Suppositories/Vagitories



Suppositories/vagitories production involves the making of the active substance suspension in special bases such as waxes. These bases solidify at room temperature and retain their shape formed in the mold, which makes them suitable for application in body cavities.

For the filling of suppository/vagitory to be continuous after completion, the temperature of the mass must be maintained at  $38\pm 2^{\circ}\text{C}$ . The process involves a torpedo shape formed in the molds through which passes an aluminum strip, into which the prepared mass is poured through dosing needles.

The endless conveyor belt of filled torpedo shapes loops through the part of the machine where it gradually hardens. Exiting the machine, it is tamped down with batch and expiration date stamped on the top of the strip and cut to the set strip size. The formed strips are transported in plastic crates to the Secondary Packaging Plant.



#### 4. PURIFIED WATER PRODUCTION AND DISTRIBUTION (PW)

Purified water is the starting material in the production of drugs, directly affecting the quality of the final product. It is used for producing drugs, preparing disinfectants and reagents, and washing production equipment. As a result,

GMP requirements are implemented in all stages of sourcing, development, and validation of the system.

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

The purification stages within the pre-treatment include:

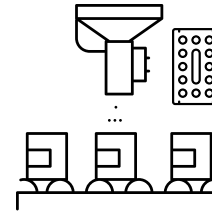
1. *prefiltration of drinking water,*
2. *oftening,*
3. *filtration,*
4. *dechlorination by UV radiation.*

The treated water is further purified by the process of reverse osmosis, which removes 99% of impurities, membrane degassing (to remove CO<sub>2</sub>), and ionization electrodes, which eliminate the remaining ions.

The purified water system is intended for continuous operation 24/7, because the key requirement is to preserve the microbiological quality of water, which is achieved by continuous circulation.

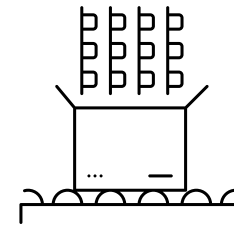
The produced purified water is collected in a tank, from where it is distributed by a pump to consumer points, and then returned to the tank. This achieves continuous circulation.

The water temperature is maintained in the range 15–20 °C, which is yet another preventative measure against microbiological growth.



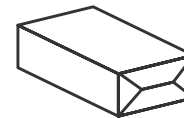
#### 5. TABLET PLANT

The production process of steroid tablets involves several stages: making powders, dry or wet granulation, tableting, film coating, and further secondary packaging.



#### 6. STARTING AND PACKAGING MATERIALS WAREHOUSE

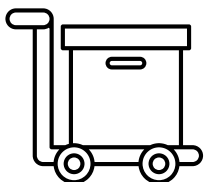
The production process starts with receiving batch-measured raw materials from the starting materials warehouse, and then transporting them through buffers/ bandpasses to the production area/white zone.



#### 7. SECONDARY PACKAGING PLANT

The dosage forms production at the pharmaceutical factory is fully organized so that the production and primary packaging of individual dosage forms take place in the plant's white zones, and that the secondary packaging is finalized in the Secondary Packaging Plant.

Once the transport packages on pallets are formed and the finished products are transported to the warehouse, the production process is brought to its completion.



## 8. FINISHED PRODUCTS AND WHOLESALE WAREHOUSE

All finished products that arrive in the finished products warehouse are quarantined until the sample testing at Quality Control is completed and the Qualified Pharmacist in charge of the drug batch launch (QP) approves the batch for the market.

The finished products warehouse is arranged as a rack warehouse that uses SAP EWM to track goods. The finished products warehouse and the starting materials warehouse are fully mapped for temperature and relative humidity monitoring

In addition, there are dedicated areas with appropriate access control for substances/products under special supervision, as well as dedicated areas for arrival, sampling, weighing, etc.

**THANK YOU FOR VISITING US!**





**Galenika**

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DEDICATED TO HEALTH**