



Galenika

**PLANT
TOUR**



FACTORY FACTS



Galenika

Galenika a.d. Belgrade was founded on July 18, 1945. The young company with only forty-three employees started to expand and grow at full tilt, quickly coming to be a major player in the pharmaceuticals market of the Yugoslavia of the time. Today, Galenika is part of the Brazilian Grupo NC, which also includes EMS — Brazil's biggest pharmaceutical company and one of the largest pharmaceutical companies in all of Latin America.

Galenika is a leader in the Serbian pharmaceuticals market, and with its 2021 launching in Albania and Kosovo, the company now has operations covering the entire Western Balkans. That same year, we set up a company in Hungary — the biggest pharmaceuticals market in Central and Eastern Europe. Galenika's products are available also in other European countries, as well as in the Middle East and North Africa (MENA).

FUN FACTS

Galenika was the fourth company to start making penicillin in the world, back in 1947.



The company has fifty products with a tradition and lasting quality for more than half a century.



Galenika's beauty product Jekoderm is the oldest national trademark that is still in use today. The trademark was registered in 1953.



QUALITY ASSURANCE

The pharmaceutical quality assurance is an essential component for building up competitiveness and opening the door to the global drug market, while implementing quality standards is prerequisite across the organization.

The production process for dosage forms is the most heavily regulated industry, which is why these processes take place under tightly controlled conditions that are defined by GMP standards (Good Manufacturing Practice). The company applies its effective quality management system in line with the best practices through its implementation of GMP, ISO, and HACCP standards.

PRODUCTION

The production process begins with the quality control of raw material inputs, which precedes the production itself, followed by packaging, storage, and shipping of finished products to the market. Every step — from raw materials input to finished product distribution — involves checkpoints that help to ensure that our factory delivers high-quality products to the market.

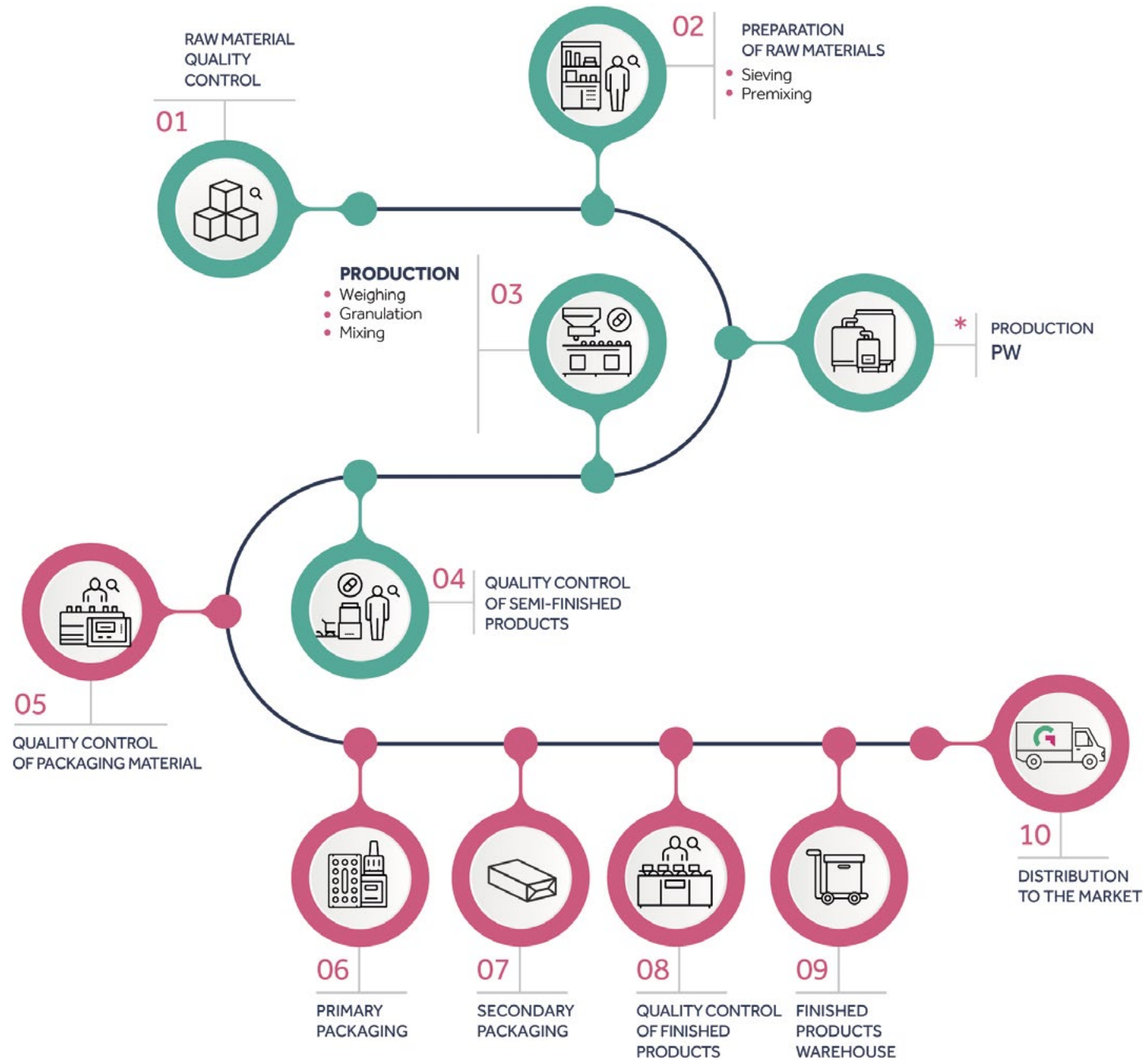
PRODUCTION CAPACITY

Dosage forms for all our markets come from two factories in Belgrade. The factories' total capacity stands at one hundred million packages a year.

The production activities take place in classified cleanrooms located in controlled areas.

- 1. THE WHITE ZONE** represents the classified and/or controlled areas for activities that involve open products (weighing, mixing of intermediates, encapsulation, tableting, pouring, filling, etc.).
- 2. THE GRAY ZONE** represents controlled areas for secondary packaging activities.
- 3. THE BLACK ZONE** represents areas with no production activities (warehouses, offices, technical floor).

The solid dosage forms factory (SDFF) is a modern production facility spreading over 10,000 m² that meets all required world-class standards, which allows Galenika to market its pharmaceutical products globally. The factory functions in line with the most stringent industry requirements and holds the national GMP, as well as EU, Ukrainian, and Russian GMPs. Furthermore, the factory holds the ISO 9001:2015 and HACCP certificates for the production and sale of dietary products. The SDFF is intended for the production of non-beta-lactams in the form of tablets, film tablets, coated tablets, and capsules. In addition to drugs, the SDFF also produces food supplements.



THE PRODUCTION PROCESS TAKES PLACE USING STATE-OF-THE-ART HIGH-CAPACITY EQUIPMENT MADE BY THE WORLD'S TOP MANUFACTURERS.

The factory was designed and built in accordance with regulations concerning quality, safety, and protection against cross-contamination in drugs production.

The air is filtered in line with the current GMP requirements. Entering the high dust risk production areas involves bandpasses where the operators change their work clothes, and the material transport system during the production process is completely sealed off.

The structural mezzanine ensures the materials' gravity flow, while where this is not possible, a vacuum-sealed transport system is used.

Through the fully automated raw materials and packaging materials warehouse spread over 800 m², the approved materials coming from the starting and packaging materials warehouse enter the factory's production cycle.





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