

Advanced cGMP manufacturing and fill-finish capabilities for specialized parenterals

Production and filling of liquids, powders, or suspensions into 2 mL to 50 mL vials



Versatile and reliable filling lines and cGMP manufacturing can enable the production of highly potent or sensitive drug products, as well as vaccines, gene therapy technologies and personalized medicine. As the number of drug products requiring advanced drug delivery technologies to deliver small molecules, peptides, proteins, and nucleic acids increases, the need to address manufacturing challenges becomes crucial.

Evonik is a global CDMO for advanced drug delivery with decades of expertise in complex parenterals. Over the years, we have developed capabilities in areas such as continuous microencapsulation, precise hot melt extrusion, liposomal extrusion, and microfluidics.

Our range of CDMO services are available to support customer projects from drug discovery and preclinical studies through to the large-scale GMP production and aseptic filling of the final drug product – whether liquid, suspension or powder.

Integrated services for volume flexibility, quality consistency and supply security

cGMP MANUFACTURING CAPABILITIES

- cGMP production for clinical batches and commercial products
- Specializing in advanced parenteral dosage forms such as lipid nanoparticles, microparticles, nanoparticles and implants
- Full support in process development, engineering and scale-up
- Aseptic processing performed in Grade A isolators
- Microencapsulation of small molecules and biologics for systemic or localized drug delivery
- Hot melt extrusion technologies for implants and other forms
- Handling of high potency drug substances to $0.01 \mu\text{g} / \text{m}^3$ (OEL)



ASEPTIC FILLING CAPABILITIES

Fully integrated, automated commercial filling line

- Powder, liquid, and suspension filling at up to 3,600 vials per hour
- Filling from 0.5 mL to 45 mL (liquid) / 40 mg to > 1500 mg (powder)
- Aseptic lyophilizers with up to 4.7 square meters of shelf space
- Integrated segments for washing and sterilization, filling, lyophilization, crimp and seal, and external vial wash



Filling lines for clinical batches

- Liquid, suspension and powder vial filling with lyophilization
- Suitable for use with vial sizes from 2 mL to 50 mL
- Filling from 0.5 mL to 30 mL (liquid) / 40 mg to > 1 g (powder)
- Suitable for batch sizes of up to 10,000 vials

This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

Evonik Operations GmbH
Health Care Business Line
Drug Delivery & Medical Device Solutions

healthcare@evonik.com
evonik.com/healthcare