

Advanced cGMP manufacturing and filling capabilities for specialized parenterals

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



Evonik Birmingham Laboratories

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 microparticles, nanoparticles, liposomes 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 >1g (powder)
- Suitable for batch sizes of up to 10,000 vials



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