

Custom Bulk Packaging for Pharmaceutical Raw Materials

ILC Dover's custom chemical bulk packaging service offers high-purity, raw materials in precise amounts for cGMP manufacturers in a variety of ready-to-use configurations.

Managing bulk chemicals is a significant source of risk, overhead, and direct labor costs for pharmaceutical and biopharmaceutical manufacturers. ILC Dover's custom bulk packaging service eliminates costs, overhead, and contamination risk with prepackaged raw materials at controlled, specified weights or volumes.

Benefits

Scalability: From grams to metric tons, ILC Dover's flexible containers provide a chemically identical, high-purity contact surface to streamline process development, scale-up, and validation.

Efficiency: Eliminates costs and contamination risks of repeatedly moving and accessing bulk raw material containers and cleaning intermediate containers.

Consistency: Trusted weights reduce variability and nonconformance risks.

Flexibility: Available with standard high-purity chemicals, containers, and connections to seamlessly integrate into many processes.

Customizability: ILC Dover's containers can be customized to meet the needs of your process, or other containers of choice can be sourced.

Applications

Media and Buffer raw materials

WFI quality Water

Sterile saline and buffers for downstream purification and polishing

Sterile saline, buffers, emulsifiers for final formulations

Quality

Containers are filled in controlled environments

Facilities are certified to ISO 9001:2015 and 13485:2016 Quality Systems

Quality Systems meet FDA 21 CFR 820 cGMP Requirements



EZ BioPac® power packaging

Standard Raw Materials, Containers, & Connections

Raw Materials

Powders	Liquids
<p><u>Salts</u> Sodium Chloride Potassium Phosphate Sodium Acetate Sodium Phosphate Potassium Acetate</p> <p><u>Buffers and pH Control</u> Sodium Hydroxide Tris / Tris HCl Guanidine HCl HEPES Urea</p> <p><u>Sugars</u> Sucrose Galactose Trehalose Glucose Dextrose Mannitol</p> <p><u>Amino Acids</u> L-Arginine L-Glutamine L-Histidine Glycine L-Methionine L-Valine L-Leucine L-Isoleucine</p>	<p><u>Carriers</u> WFI Quality Water Cell Culture Water Molecular Grade Water Saline Media</p> <p><u>Buffers and pH Control</u> Hydrochloric Acid Acetic Acid Sodium Hydroxide (up to 50%) Tris Tris HCl Guanidine HCl HEPES Urea</p> <p><u>Alcohols[†]</u></p> <p><u>Peroxides[†]</u></p>
<p>Sizes and Containers</p> <p><u>EZ BioPac®*</u>: up to 100 L <u>Drums</u>: 50 kg <u>Pails</u>: 12 kg and 25 kg <u>Bottles</u>: 500 g and 1,000 g</p>	<p><u>Liquid Bags[†]</u>: up to 200 L <u>Bottles</u>: 1 L and 4 L</p>
<p>Connections</p> <p><u>EZ BioPac®*</u>: Stretch Fit Flange-gasket AVAX Butterfly Valve</p>	<p><u>Liquid Bags[†]</u>: Luers MPCs</p>



* EZ BioPac® containers are made of ArmorFlex® Films, which are rugged high-purity polyethylene blends with extensive testing data available upon request.
 † ILC Dover's Liquid Single-Use Bags are made of Renolit Solmed 9101, a medical-grade polyethylene-contact film with an internal oxygen-barrier layer.
 ‡ Only available in bottles.