Your lyophilization destination.
Our world.

Lyophilization Cycle Development and Optimization Services

At PCI, ensuring life-changing medicines reach those who need it most is our highest priority. As a truly integrated global CDMO, we are manufacturing, packaging and supply chain experts, harnessing our experience and expertise to deliver you a seamless solution with the ultimate aim of improving the lives of patients.

PCI is uniquely positioned to both develop your lyophilization cycle from the beginning or optimize the existing cycle, providing you with a commercially desirable yet economical process.

As a lyophilization development specialty house, we are market leaders offering one of the largest lyophilization capacities in the industry with over 30 lyophilizers.

Lyophilization Services Include:

Thermal Characterization

Cycle development begins with understanding the critical temperatures of the formulation by utilizing:
- Modulated Differential Scanning Calorimetry (mDSC)
- Freeze Dry Microscopy (FDM)

Once we have determined the thermal properties of your formulated product, we use the Glass Transition (Tg), Eutectic Temperature (Te), Collapse Temperature (Tc) and Re-crystallization Temperature (Tcry) data to develop the nominal drying conditions for the lyophilization cycle parameters.

Intentional Collapse

To deliver a commercially robust lyophilization process and ensure the finished product consistently meets the finished product CQAs at release, we perform an “Intentional Collapse Study” (ICS) during the final stages of lyophilization development. The Process Development team will perform the ICS study to intentionally collapse the product to fully understand the potential points of failure in the lyophilization cycle.

Conserving Valuable Drug Substance

If limited material is available for cycle development, we can develop an experimental plan based on the available API. By establishing the testing plan for development activities, we can use a placebo or small amounts of drug substance in the early stage feasibility before the final confirmatory lyophilization runs.

Overview

Cycle Optimization

Life-cycling the nominal lyophilization cycle parameters, we will specifically optimize the lyophilization cycle for your product, optimizing for low residual moisture, cake appearance, reconstitution, and total run time. Optimizing the cycle for total run time can lead to cost efficiencies over the life-cycle of your product.

Toxicology Batches

One important step of your clinical program will be the required toxicology studies. PCI is able to deliver toxicology material, supplying you with the information needed to support pre-clinical and your IND submission.

Solvent Lyophilization

If your manufacturing process requires the aid of organic solvents to increase solubility, we can evaluate such solvents as tert-butyl alcohol, acetonitrile, DMSO, or ethanol. We have the experience to safely develop and transfer the manufacturing processes to our GMP manufacturing facilities and work closely with our Environmental Health and Safety (EHS) team to determine the volumes we can safely handle.