



PHARMACEUTICS KNOW-HOW™

# LYOPHILIZATION CAPABILITIES



## SYNERGIES:

In order to provide the best possible transfer between the development-scale process and the production-scale process, we utilize Millrock lyophilization technology in the lab and in the production unit. This allows for synergy of technology and engineering factors critical for scale-up and transfer activities.

## CAPACITY:

Our development-scale lyophilizer has a chamber suitable to produce a range of different batch sizes for evaluation of process parameters or producing supplies for various studies. These studies include but aren't limited to development of analytical methods, production of reference standards, non-pivotal toxicological supplies, and evaluation of stability.

## ADVANCED SOFTWARE:

The Accuflux™ and Autodry™ features for our Development-scale unit are powerful innovative tools that offer process control and monitoring for both the freezing and primary drying steps, enabling analysis and process optimization. This software is an improvement from much older software technologies on the market with other brands. Pii's unit is also set up for the use of Freezebooster™ technology.

Accuflux™ is a patented method of process monitoring and control that provides a direct measurement of heat flux. AccuFlux provides a new and valuable tool to understand the thermal events occurring during the freezing and primary drying steps. With direct and continuous measurement AccuFlux provides a continuous stream of your critical process parameters, for use in protocol improvement and transfer.

AutoDry™ is a patented method to control primary drying based on the product temperature. Optimize your cycle early for the highest throughput in the lab and in manufacturing.

FreezeBooster™ controlled nucleation enables the ability to study freezing approaches and its effect on the product and product cycle. Create a homogeneous cake across the batch to improve product quality and reduce primary drying time.

## CAPABILITIES:

Experienced and trained lyophilization professionals at Pii with experiences in the management of challenging formulations and product configurations. Our development-scale unit also has a sample thief for optimizing secondary drying.

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Pii provides customized and flexible solutions, across several dosage forms and has experience with a broad range of compounds. For over twenty-five years Pii has been supporting its pharmaceutical partners with extensive technical capabilities, know-how, and the highest level of customer service. With more than 400 development programs completed, Pii's scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities and knowledge-base, allow us to work with potent compounds and hormones, develop complex dosage forms, and support varied manufacturing processes.

## CAPABILITIES

- Sterile (vials, syringes, lyophilized)
- Injectables (including viscous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Topicals
- Potent compounds, hormones, cytotoxics
- Solid dispersions (HME and spray drying)
- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro & Nanotechnologies

## SERVICES

- Preformulation Testing
- Dosage Form Development
- Analytical Development & Testing
- CTM Manufacturing
- Commercial Manufacturing
- Aseptic Filling
- Clinical Packaging and Distribution
- Regulatory Support



FORMULATION  
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PROCESS AND  
MANUFACTURING  
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COMMERCIAL  
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QUALITY  
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PROJECT  
MANAGEMENT  
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REGULATORY  
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