

## **Continuous Freeze-Drying of Pharmaceuticals and Biopharmaceuticals in Unit Doses**

Technology #19494

### **Applications**

This technology is a freeze-drying technique with potential applications in pharmaceutical and research reagent manufacturing.

### **Problem Addressed**

Freeze-drying (aka lyophilization) is commonly used to stabilize pharmaceuticals and research reagents for distribution and storage. Freeze-drying is very time intensive, requiring up to 300 hours to complete one cycle. Additionally, pharmaceuticals are freeze-dried in large batches, which can result in a high level of vial-to-vial variation in quality depending on the location of the vial in the lyophilization chamber. There is therefore a need for faster freeze-drying manufacturing techniques that result in more uniform final products.

### **Technology**

This technology uses a continuous manufacturing line to freeze-dry pharmaceutical formulations. To freeze-dry a drug, the samples are (1) loaded into vials, (2) frozen, undergo a two-step drying process of (3) primary drying and (4) secondary drying, then are (5) backfilled/stoppered. In traditional freeze-drying manufacturing, these steps are done in large batches and require manual handling between steps, which results in long dead times. This technology performs all of the freeze-drying steps in a fully automated, continuous manufacturing line that includes filling, freezing, drying, and backfill/stoppering modules. This continuous freeze-drying system has three major improvements over batch freeze-drying. First, the continuous freeze-drying process is up to 5 times shorter than a traditional batch freeze-drying cycle. Secondly, the continuous freeze-drying line is autonomous and internally sterile, which cuts down on labor and increases the safety of the final product since because samples do not need to be manually transferred between steps. Finally, since all the samples pass through the same path, the final products have greater uniformity than those produced using batch freeze-drying. In summary, this technology can greatly improve the quality and speed of manufacturing for lyophilized drugs and research reagents.

### **Advantages**

- Up to 5 times shorter cycle time than batch freeze drying
- No manual handling, increasing safety and ease-of-use
- Greater final product uniformity in comparison to batch lyophilized products
- Modular system that can be adapted to each product's manufacturing needs

### **Categories For This Invention:**

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Life Sciences

Research Tools

Protein & Protein Chemistry

Therapeutics

Antibody (Therapeutics)

Peptide

Protein

## **Intellectual Property:**

Freeze drying methods and products

PCT

2018-204484

Freeze drying methods and products

US Patent Pending

## **Inventors:**

Bernhardt Trout

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## **Publications:**

From batch to continuous: freeze-drying of suspended vials for pharmaceuticals in unit-doses

Industrial & Engineering Chemistry Research

Volume 58 Issue (4), 2019, pages 1635-1649

Achieving continuous manufacturing in lyophilization: Technologies and approaches

European Journal of Pharmaceutics and Biopharmaceutics

Volume 142, 2019, pages 265-279

## **External Links:**

Trout Group

<http://troutgroup.mit.edu/>

## **Image Gallery:**



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