

POLARDRY® ELECTROSTATIC DRYING: Single-Step Solvent Removal and Drying of Peptides

CASE STUDY

SOLVENT REMOVAL IN PEPTIDE MANUFACTURING

Peptide therapeutics have become increasingly prominent in the pharmaceutical landscape, offering breakthrough solutions for complex diseases. Organic solvents are extensively used in upstream processes such as chemical synthesis, cleavage, and downstream operations, including separation and purification. Consequently, the final liquid peptide product often exists in a solvent or solvent-water mixture, necessitating efficient and precise solvent removal techniques.

Obtaining peptide powder using current drying processes such as lyophilization and conventional spray drying pose additional challenges when the peptides are in solvents. The solvents need to be removed prior to drying, making it a two-step process. Not to mention another post-processing step for milling, particle formation, and processing powders to contain residual solvents below regulatory limits.

POLARDRY® ELECTROSTATIC DRYING

Fluid Air's PolarDry® electrostatic drying (ESD) is a new, innovative technology that can efficiently remove solvents from peptides and other therapeutics. ESD is a continuous, scalable process that uses an electrostatic charge to effectively remove water and solvents, resulting in dry peptide powders that do not require post-processing.

Lyophilization Workflow:

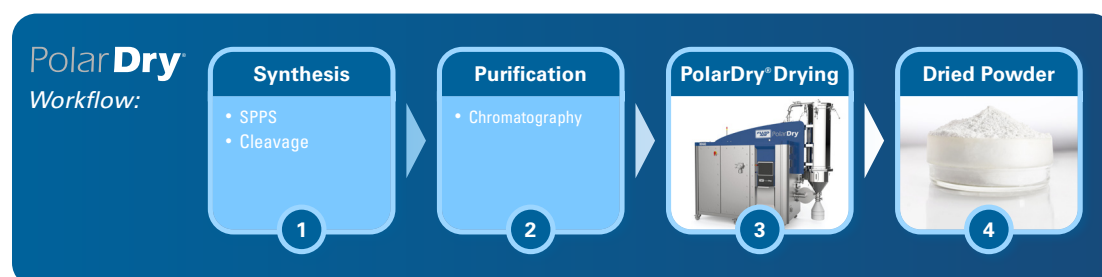
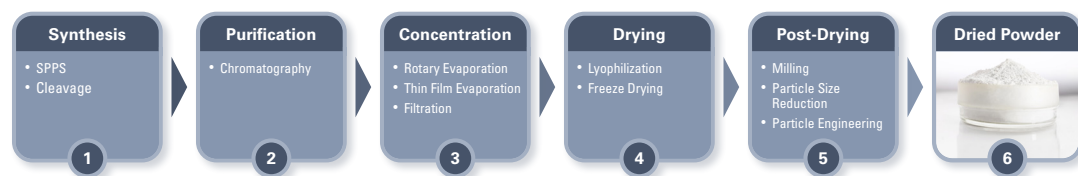


Figure 1. Lyophilization workflow versus PolarDry® workflow

HIGHLIGHTS

Efficient removal of solvents from peptides and other pharmaceutical drugs

Low-temperature processing with a patented electrostatic charging mechanism that enhances drying kinetics

After the PolarDry® process, residual solvent in powders is below ICH limit requirements

Continuous, single-step system, facilitating immediate powder formation

SINGLE-STEP SOLVENT REMOVAL AND DRYING PEPTIDES

POLARDRY® FEATURES

PolarDry® electrostatic drying technology combines low-temperature processing with a patented electrostatic charging mechanism that enhances drying kinetics. The risk to explosion is prevented by using nitrogen gas for the drying and processing. As a continuous, single-step system, PolarDry® facilitates immediate powder formation and collection, offering true “powder on demand” capability. Its flexible system design accommodates various formulations, from aqueous to solvent-based mixtures, across both low and high solids concentrations. Additionally, all PolarDry® units work under a slight negative pressure making it optimal for containment of high potent drugs.

RESIDUAL SOLVENTS

While solvents are essential during peptide synthesis, their presence in the final formulation poses safety and stability risks. Residual solvents may contribute to the formation of harmful byproducts and may negatively affect patient acceptability. Trials conducted in Fluid Air’s pilot labs demonstrated that the bovine serum albumin (BSA) surrogate formulation in a 50:50 acetonitrile-water mixture can be successfully dried at all scales, resulting in dry powders with residual acetonitrile levels below the 410 ppm limits when tested per the United States Pharmacopoeia USP <467> method set by the International Council for Harmonisation (ICH).



PolarDry® Model 001



PolarDry® Model 032

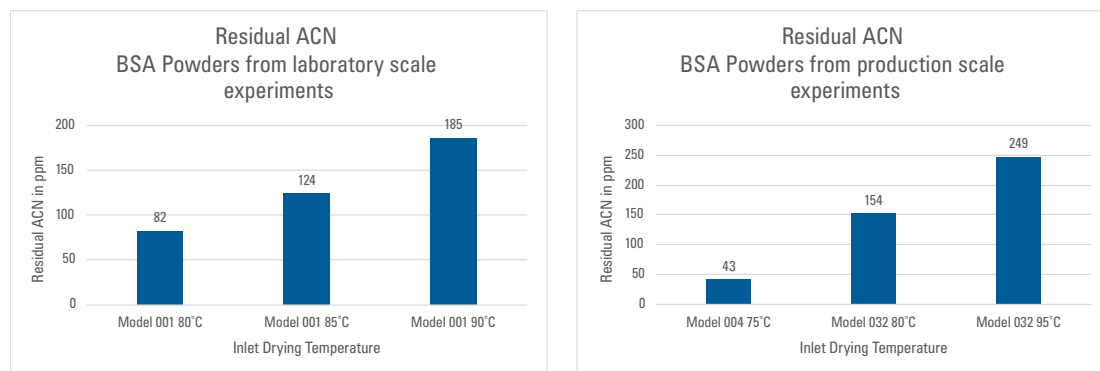


Figure 2. Laboratory scale versus production scale BSA powder drying results

CONCLUSION

PolarDry® represents a next-generation drying solution that addresses peptide manufacturing challenges with precision and efficiency. Its ability to replace lyophilization or conventional spray drying with a gentler, scalable, and compliant process positions it as a strategic advantage in pharmaceutical peptide production.

