*symbiosis
Pharmaceutical Services

Lyophilisation: A tool to enhance product stability

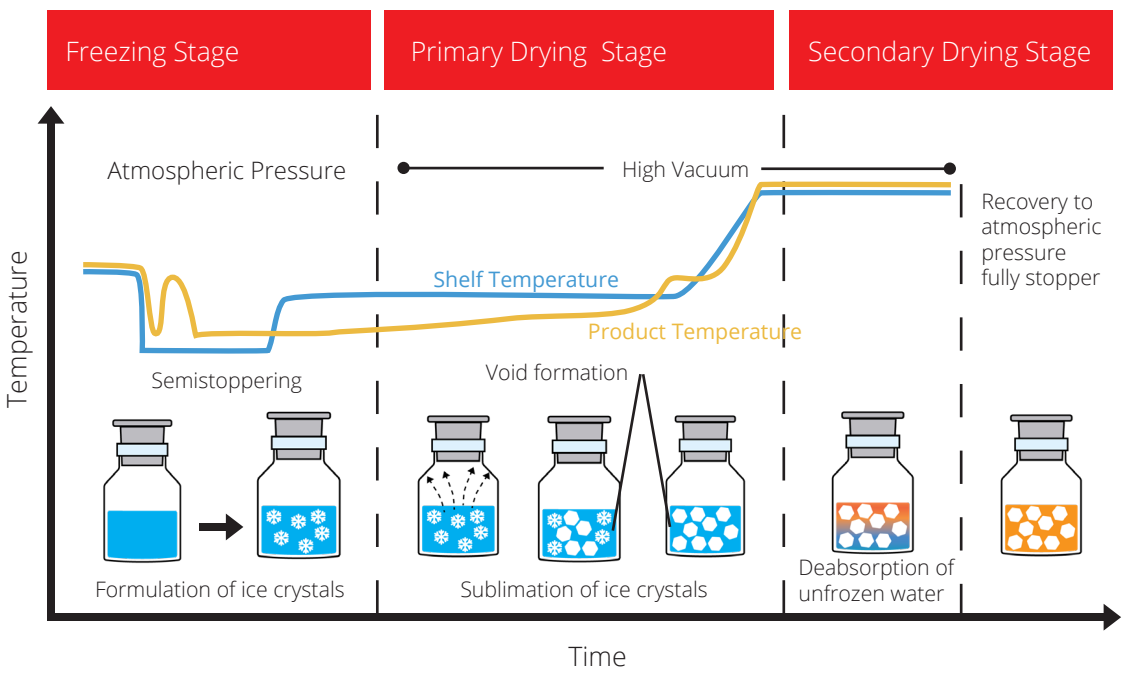
1. Definition

A stabilizing process in which a substance is first frozen then the quantity of the solvent is reduced, first by sublimation (primary drying stage) and then desorption (secondary drying stage) to values that will no longer support biological activity or chemical reactions.

2. Purpose

- To preserve the biological activity of the product
- To reduce the product weight to lower the transportation costs
- To extend the shelf life or stability
- To eliminate the need for refrigeration storage
- To get accurate, sterile dosing into the final product container

3. Process



4. Benefits

Samples can be stored at room temperature indefinitely

The process reduces weight and volume of samples making them ideal for shipping

Dissolution of the reconstituted product is both easy and rapid

The product is processed in an aseptic environment

Water is removed without heat which prevents product degradation during drying

The shelf life of the drug product is extended, and stability is enhanced

5. Pharmaceutical products suitable for lyophilisation

Small Molecules

Nucleic Acids

mAbs

Recombinant Proteins

Peptides

Cytotoxics

ATMPs/Viral Vector Therapies

Antibody Drug Conjugates

i Contact us to find out about:

- How we can design a process for aseptic lyophilisation for biologics and complex drug products
- Validation requirements and regulatory guidance for aseptic manufacturing processes
- Our well-designed validation strategy that enables efficient aseptic lyophilisation based on your DP makeup