Lyophilisation

Delivering pharmaceutical elegance and physiochemical stability with lyophilisation

Complex small molecule APIs present unique formulation and stability challenges. Lyophilisation or freeze drying, a 3-stage interconnected process involving freezing, sublimation and desorption, helps deliver these agents in a form that can be easily reconstituted and administered to the patient.

Sai Life Sciences has extensive experience in the development and optimisation of the lyophilisation process and ensures smooth scale-up of the product with the help of best-in-class equipment operated by highly trained personnel.

Highlights

- Successfully deployed lyophilisation in several critical projects
- Lyophilisation cycle development to help freeze dry heat-sensitive drugs to improve stability and enhance shelf life
- Developed customised freeze-drying programmes (or recipes) to match desired product specifications
- Digitally controlled system that ensures alignment with the defined lyophilisation process
- Prioritised safety by minimising exposure to the lyophilised substance with closed trays (covered by expanded PTFE on polypropylene)
- Optimised process parameters effectively in pilot studies enabling smooth scale-up

Best-in-class infrastructure

- **Pilot scale**
  - 30L capacity, MOC: SS316L
  - Condenser temperature: -85°C
  - Shelf temperature: -65 to +65°C
  - Maximum vacuum: 10 millitorr
- **Scale-up lyophilisers**
  - 18L and 300L capacity
  - Located in class 100,000 clean rooms
  - Maximum loading volume of 2L per tray for both units
  - Freeze drying range -50° to 70°C

S No.	Description	DLLR01-1	DLLR02
1	Capacity (Ice condensing)	18.0L	300L
2	No. of trays	9	168

For more information contact: **contact@sailife.com**