

Summary - Lyophilization

Collapse Temperature – in the lyophilization of amorphous systems, that temperature below which primary drying must occur to prevent loss of product cake structure (i.e., meltback).

Degree of Supercooling – the number of degrees below the equilibrium freezing temperature where ice first starts to form.

Eutectic Temperature – for crystalline solutes, a point of a phase diagram where all phases are present and temperature and composition of the liquid phase cannot be altered without one of the phases disappearing. Primary drying must occur below this temperature to allow for complete sublimation.

Commissioning and Qualification of Lyophilizers should include the following:

- Vacuum leak rate, maximum vacuum level, chamber pressure control, and condenser capacity are verified;
- A minimum of three temperature distribution studies on an empty chamber are conducted to confirm shelf temperature control and uniformity at three temperature ranges representing the three phases of the lyophilization cycle (i.e., freezing, primary drying, and secondary drying);
- At least one product study is conducted using simulated or actual product; and
- Media Fills are performed.

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