

# Lyophilisation - Typical CMA/CQA/CPP

## Critical Material Attributes (CMA)

- ☐ Crystalline/Amorphous.
- ☐ Cake Collapse Temp.
- ☐ Eutectic Temperature.
- ☐ Glass Transition Temperature.
- ☐ Product Resistance.

## Critical Quality Attributes (CQA)

- ☐ Cake Appearance.
- ☐ Reconstitution Time.
- ☐ Water Content.
- ☐ Assay.
- ☐ Related substance.

## Critical Process Parameters (CPP)

- ☐ Freezing temperature.
- ☐ Freezing rate.
- ☐ Annealing temperature and Time.
- ☐ Primary drying: pressure, time/time
- ☐ Secondary time: temperature/pressure/time.