

# Lyophilisation Process Development

- ❑ Quality Target Product Profile (QTPP) for Lyophilized injectable form:  
Route of administration, Dosage strength, Pharmaceutical dosage form, Container-closure system, Storage condition, Shelf life, Quality attributes (Appearance, identification, Uniformity of mass, uniformity of dosage units, reconstitution time, Residual water, API content, Related substances, Particles, Sterility, bacterial endotoxins).
- ❑ Identification and Determination of :
  - Critical Quality Attributes (CQAs).
  - Critical Material Attributes (CMA).
  - Process Parameters (CPPs).