

Fundamentals of Dissolution: Guidance for the Verification and Qualification of a Dissolution Apparatus

Day 1: March 16, 2021

- Introduction: USP, Standards Development Process, Dissolution Resources
- Dissolution Theory and Historical Highlights
- Compendial Dissolution Testing
 - Dissolution Testing in drug product monographs
 - USP General Chapter <711> Requirements
 - Harmonization of USP <711>
 - Four main dissolution apparatus used for dissolution testing

Day 2: March 17, 2021

- Qualification of Dissolution Apparatus
 - Identifying and controlling sources of variability in dissolution test results
 - Mechanical Qualification of dissolution apparatus
 - Performance Verification Test (PVT)

Day 3: March 18, 2021

- Data Handling and Acceptance Tables
- Examples and feedback regarding PVT
- Open Question & Answer Session