Project #5
Science-based
Statistical Comparison
of Dissolution Profiles

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Problem Statement

• The ability to compare dissolution profiles is important to the pharmaceutical industry.

• Possible situations include *Product release decisions*; *Equivalence decisions* as well as *Manufacturing and Optimization decisions*.

• Statistical analysis of dissolution profiles could contribute to an *integrated analysis framework* from manufacturing to bioavailability

• **Limitations of Current Methods:**
  • Largely arbitrary, without a solid statistical basis (f1 and f2)
  • Do not provide any measure of significance
  • Do not allow for simultaneous comparison of multiple profiles
  • Difficult to assess statistical effect and significance of manufacturing
Continuous development towards an Integrated Analysis Framework from Manufacturing to Bioavailability
Objectives

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Figure 1. Schematic illustration for MANOVA repeated measures for dissolution profiles.

Figure 2. A schematic illustration on level and shape of a curve.
Deliverables and Industrial Impact

- Tailored **Multivariate Statistical Methods and Procedures** for *release, equivalence* and *optimization decision* tests.
- Enabling Integrated Analysis Framework development
- Quantification of *semi-mechanistic dissolution models*
- Establishing correlations between model parameters and tablet properties.
- **Case studies, detailed tutorials**, including specific guidelines for each situation.
- Continuous Education and Dissemination activities.
- **Seamless integration** into available software packages
Q & A?