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
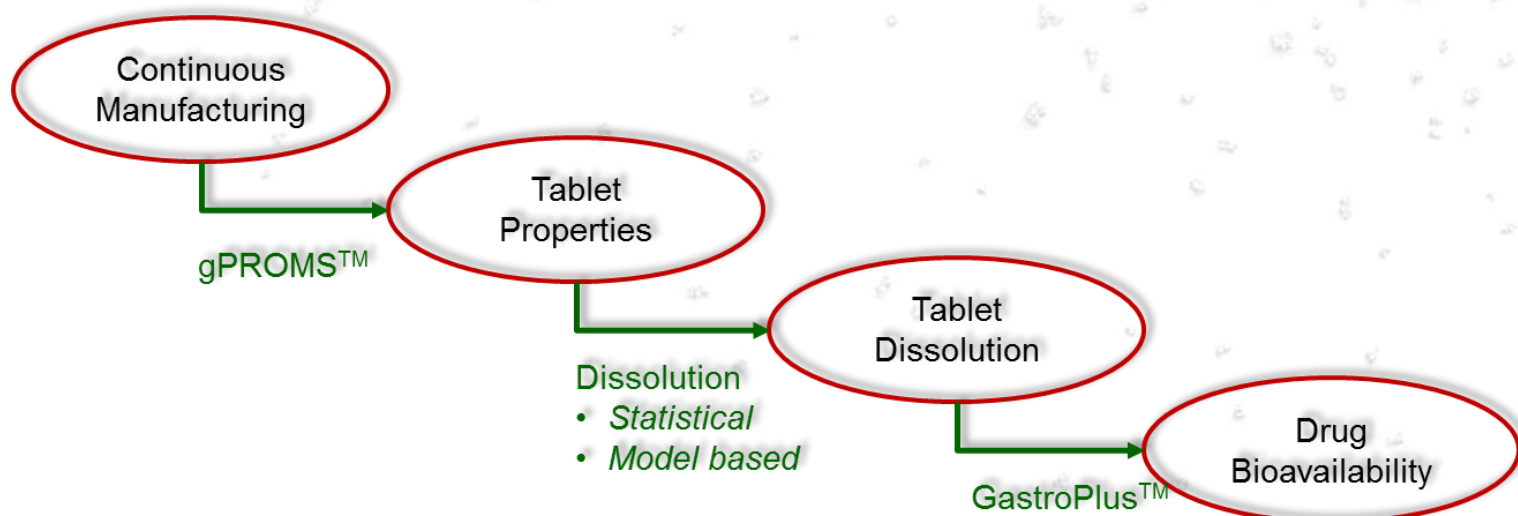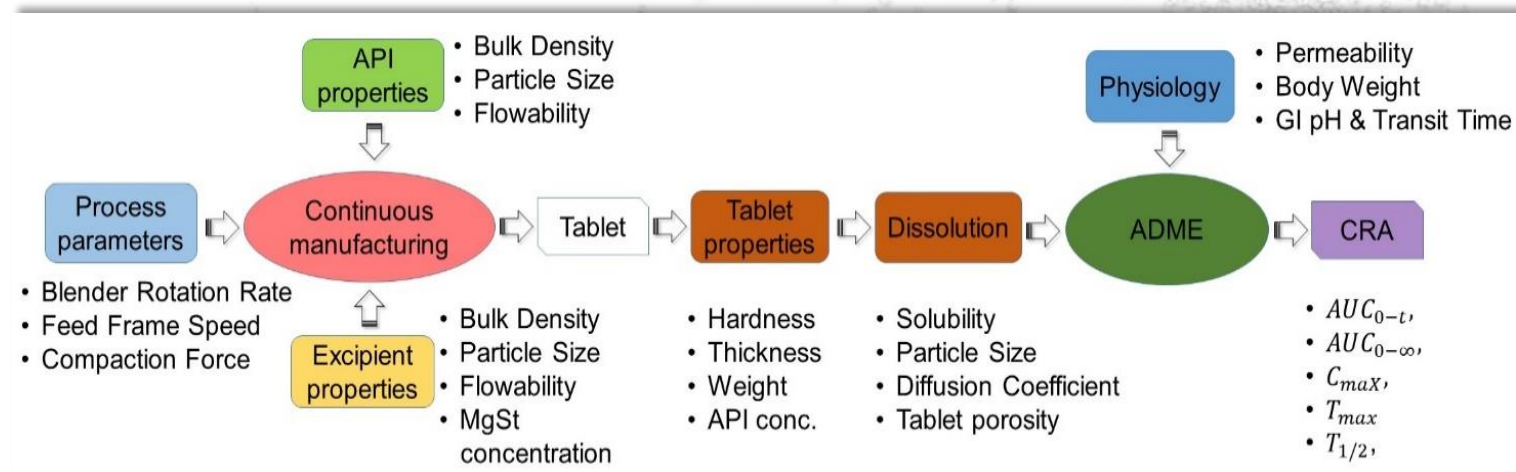
Objectives

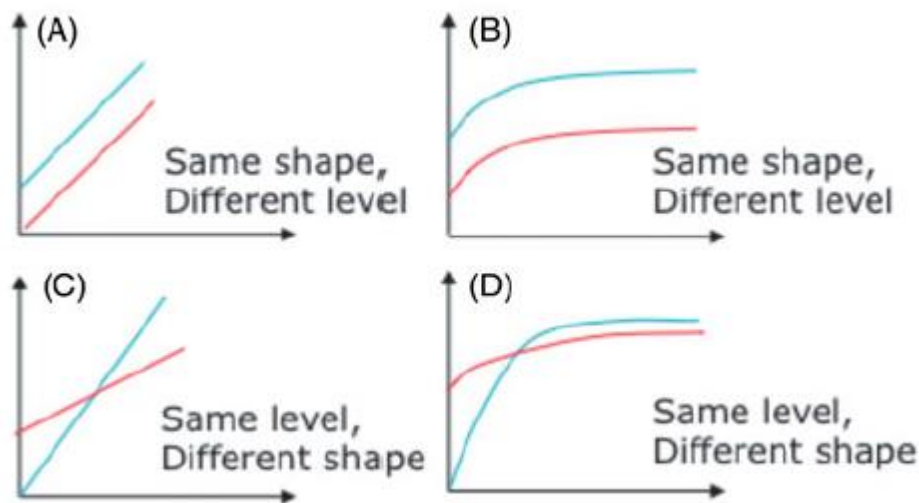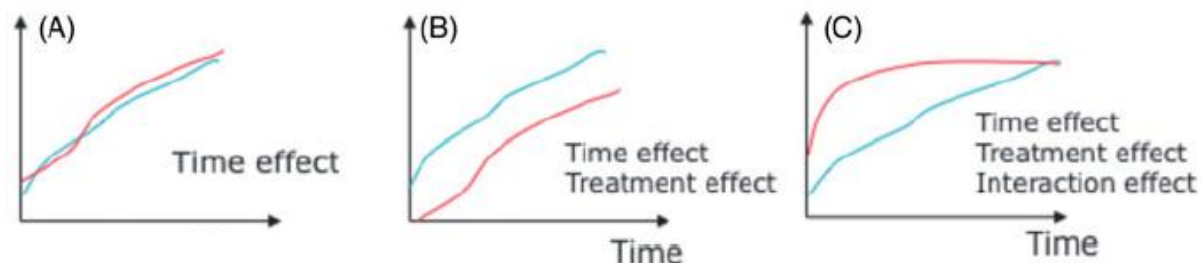Figure 1. Schematic illustration for MANOVA repeated measures for dissolution profiles.

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

RESEARCH ARTICLE

Statistical comparison of dissolution profiles

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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?