KEY POINTS

The following key points are discussed in this article:

- Dissolution is an essential step in the drug absorption from solid products. *In vitro* dissolution is primarily a function of drug solubility, the dosage form design, and the testing methodology and conditions.
- There are different mathematical models that describe dissolution phenomena.
- Various dissolution apparatus are adopted officially by pharmacopeia. The United States Pharmacopeia (USP) Apparatus I and II are the most commonly used for solid oral dosage forms.
- Different drug release mechanisms are employed in different drug delivery systems that can be described by various kinetic models.
- Comparison of dissolution profiles are often performed using statistical approaches (e.g., $f_1$ and $f_2$).
- Physico-chemical property of the drug substance, dosage form design, medium, and apparatus are important considerations in developing a dissolution method.
- *In vitro-in vivo* correlation (IVIVC) refers to a quantitative relationship between *in vitro* properties (usually dissolution) and the *in vivo* performance (e.g., drug plasma concentration-time profile) of a drug product.
- IVIVC is categorized into level A, level B, level C, and multiple level C, with level A, level C, and multiple level C being the most useful for regulatory applications.
- Considerations in establishing an IVIVC include development of a predictive *in vitro* test, *in vivo* study design, model building, and model validation.
- A level A IVIVC may be established by a two-stage (deconvolution followed by correlation) approach or a single-stage (convolution followed by comparison of drug-plasma profile) approach.
- Internal or external validation of IVIVC models is required depending on specific situations.
- When an IVIVC is established and validated, *in vitro* dissolution becomes a surrogate for the *in vivo* performance of the drug product. Therefore, it can be used to determine meaningful dissolution specifications, to obtain waivers for bio studies required for certain scale-up and post-approval changes (SUPAC).
- The success of IVIVC exploration depends on a multitude of factors including the physico-chemical, biological, and pharmacokinetic properties of the drug molecule, the dosage form design, and their interplay in the gastrointestinal tracts. It remains a challenging task.
- Validation personnel should be especially vigilant regarding changes or variations in materials, process, equipment,
and scale that may impact dissolution, particularly for modified-release products.

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