Parsolex
PARTNER SOLUTIONS EXCELLENCE

Dissolution and Drug Release Testing

Dissolution testing refers to the performance of an *in vitro* test method to measure the release of an active pharmaceutical ingredient from a solid oral drug product dosage form (*e.g.*, tablets, capsules, or liquid suspensions) to an aqueous-based solution. Drug release testing, a term often used synonymously with dissolution testing, extends the concept of dissolution testing to solid non-oral drug product dosage forms (*e.g.*, injectable suspensions, suppositories, or transdermal creams).

In vitro dissolution testing (or drug release testing) has emerged as a critical test methodology used throughout the life cycle of these solid oral and non-oral drug products. Applications for *in vitro* dissolution testing include the following:

- Predict and model the *in vivo* performance (or bioavailability) of the drug product
- Guide formulation development
- Monitor the effects of changes to the production process
- Demonstrate bioequivalence
- Monitor lot-to-lot quality of the drug product
- Serve as a quality control test

Bioavailability is defined as the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of biological action. Bioavailability can be measured by collecting samples from the systemic circulation (*e.g.*, blood, serum, or plasma) and determining the concentration of the active (or metabolites) in those samples. *In vitro–in vivo* correlation ("IVIVC") describes the relationship between an *in vitro* diagnostic of the drug product (*i.e.*, dissolution or drug release testing) and an *in vivo* measurement. Once an IVIVC is established, the *in vitro* test can serve as a surrogate for assessing bioavailability.

In vitro dissolution data are typically generated from drug product material used in pivotal clinical or

bioavailability studies. *In vitro* dissolution data are also generated whenever significant changes are made to the drug product. Changes may include modifications to the formulation or to the sourcing of any of its components, such as a new supplier or different particle size distribution. Changes may also include modifications to the process, such as a scale-up of the process or change in venue.

In vitro dissolution studies are also used to demonstrate bioequivalence ("BE"). To receive approval for an abbreviation new drug application ("ANDA"), an applicant must show that the new drug product is bioequivalent to the reference listed drug. BE must be established through the combination of pharmacokinetic, pharmacodynamic, clinical, and/or *in vitro* dissolution (or drug release) studies.

Finally, dissolution testing is used as a quality control test to evaluate the lot-to-lot variability of a manufactured drug product and screen for any deficiencies with *in vivo* bioavailability. The dissolution test may be modified at this stage of the drug product life cycle to allow for proper discrimination of compliant and non-compliant manufactured lots of the drug product.

3000 Kent Avenue, Suite 1510
West Lafayette, IN 47906-1169
Located in the Purdue Research Park

info@parsolexinc.com
www.parsolexinc.com

Main: 765.464.8414
Fax: 765.464.8408

Parsolex
PARTNER SOLUTIONS EXCELLENCE

Dissolution and Drug Release Testing

Dissolution Testing

Parsolex provides dissolution testing using qualified, state-of-the-art dissolution equipment, including Apparatus 1 (basket) and Apparatus 2 (paddles) configurations as described in the United States Pharmacopeia ("USP") ⟨711⟩ *Dissolution*. Our scientists have extensive experience conducting dissolution studies for a broad range of drug products using both automated and manual sampling techniques.

Our dissolution testing services span all phases of drug development. Parsolex uses dissolution testing during formulation design and selection as an essential tool to compare the performance of different prototype formulations and manufacturing parameters during pre-clinical development. The data generated guide our scientists in the selection of appropriate excipient types and compositions and informs the manufacturing process conditions that are needed to achieve a specific drug product release profile that will meet BE requirements.

We perform dissolution testing to reveal differences in performance during drug product development and as a validated control method for release testing. Dissolution rates are highly dependent on the intrinsic properties of the API solid form (*e.g.*, solubility) and the process parameters used for drug product manufacture (*e.g.*, particle size distribution, tablet hardness and friability). Therefore, characterization of the dissolution rates of different formulations in various media can guide excipient selection and identify critical process control parameters to achieve the desired release profiles for an immediate, controlled, or delayed-release formulation.

As a quality control test, Parsolex uses dissolution tests to assess batch-to-batch consistency of solid oral dosage forms manufactured for clinical trial material ("CTM") and for commercial use. To this end, Parsolex can perform dissolution testing in accordance with USP ⟨711⟩ and regulatory guidelines for solid dosage products, as well as develop and validate fit-for-purpose dissolution tests leveraging our experience and knowledge of a wide range of dosage forms.

Method Development and Validation

When existing dissolution test methods are available, Parsolex can also help facilitate analytical method technology transfer of these test methods and perform appropriate interlaboratory protocols for comparative testing or revalidation of the test method.

Whether the dosage form is immediate release or modified release, we offer dissolution method development support. Our approaches to dissolution test method development seeks to understand the key factors that influence drug release including intrinsic physical and chemical properties of the API (*e.g.*, solubility and permeability), impact of excipient type and composition, and properties of the manufactured drug product (*e.g.*, particle size distribution).

Mindful of the goals of our clients, Parsolex seeks to develop test methods that are sensitive to critical performance attributes affecting release rate, including changes in the product that can occur after elevated temperature and humidity stress.

Why Choose Parsolex?

Parsolex offers dissolution testing of solid oral dosage forms with a focus on the client experience. We are committed to fully understand our clients' requirements and to deliver each project on agreed upon timelines. Parsolex brings in-depth experience with analytical technologies for testing pharmaceuticals and a comprehensive understanding of the latest regulatory guidance. We are committed to the highest level of quality and attention to detail to make sure each dissolution study is successfully executed.

3000 Kent Avenue, Suite 1510
West Lafayette, IN 47906-1169
Located in the Purdue Research Park

info@parsolexinc.com
www.parsolexinc.com

Main: 765.464.8414
Fax: 765.464.8408