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Bioequivalence & Bioavailability International Journal
ISSN: 2578-4803

From Dissolution Profiles to Clinical Exposure: Bridging In Vitro and In Vivo Bioequivalence

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Short Communication
Volume 10 Issue 1
Received Date: May 29, 2026
Published Date: June 08, 2026

Abstract

Dissolution testing is an essential component of pharmaceutical development and bioequivalence assessment because it provides information about the rate and extent of drug release from a dosage form. However, dissolution occurring in a laboratory vessel does not automatically represent the complex sequence of physiological events that determines drug exposure after administration. Differences in gastrointestinal pH, fluid composition, gastric emptying, intestinal transit, permeability, metabolism, and transporter activity can influence the relationship between in vitro drug release and in vivo systemic exposure.

Keywords: Dissolution Testing; Bioequivalence; Bioavailability; In Vitro–In Vivo Correlation; IVIVC; Drug Release; Pharmacokinetics; Clinical Exposure; Biopharmaceutics; Formulation Development

Introduction

Dissolution testing occupies an important position between pharmaceutical formulation development and clinical pharmacokinetic evaluation. For an orally administered solid dosage form, the drug generally needs to be released from the formulation and become available for absorption before systemic exposure can occur. Consequently, dissolution characteristics can influence the rate and extent of drug availability and may provide an important indication of formulation performance [1].

Regulatory guidance recognizes several purposes for dissolution testing, including formulation development, quality control, comparison of products, and, under appropriate circumstances, support for biowaiver decisions. However, an in vitro dissolution experiment represents a simplified environment, whereas drug absorption occurs within a dynamic gastrointestinal system.

The central challenge is therefore to determine how closely an in vitro dissolution profile reflects what happens after administration to humans. Bridging this gap is particularly important when formulation changes, manufacturing modifications, generic product development, or modified-release technologies are being evaluated.

Dissolution testing measures the release of drug substance from a dosage form into a specified medium under controlled experimental conditions. Properly designed dissolution methods can reveal differences in formulation composition, manufacturing processes, drug particle characteristics, and release mechanisms.

The FDA describes dissolution testing as a means of evaluating factors affecting the rate and extent of drug release and, ultimately, the in vivo performance of a drug product. This makes dissolution more than a routine quality-control measurement. When appropriately developed, it can

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function as a sensitive tool for detecting meaningful changes in product performance [2].

Conclusion

Dissolution testing provides an essential link between pharmaceutical formulation and biological performance, but the relationship between in vitro drug release and in vivo exposure is neither automatic nor universal. Drug solubility, permeability, gastrointestinal physiology, formulation characteristics, and presystemic processes can all influence the transition from dissolution to systemic exposure.

References

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