

## **2026 University of Maryland Baltimore**

### **Oral Biopharmaceutics Risk Assessment Framework (HP-00118034)**

This survey involves research, is anonymous, and is intended for pharmaceutical scientists. Only adults are to take this survey. This research survey will take approximately 25 minutes to complete. The deadline for taking the survey is Monday, March 16 2026 at 5pm ET. In order to complete this survey, consider simultaneously viewing the entire survey (as a PDF) located at [www.pharmacy.umaryland.edu/centers/cersievents/2025dissolution/survey](http://www.pharmacy.umaryland.edu/centers/cersievents/2025dissolution/survey) .

#### **Background:**

The objective of this survey is to gain insight from pharmaceutical scientists about how biopharmaceutic risks of oral solid dosage forms (e.g. tablets and capsules) are assessed and possibly mitigated to allow for high quality of manufactured products, in part via in vitro dissolution testing when necessary. Survey results will shape breakout sessions at an M-CERSI workshop on April 30 – May 1 2026 in Rockville, MD ([www.pharmacy.umaryland.edu/centers/cersievents/2025dissolution](http://www.pharmacy.umaryland.edu/centers/cersievents/2025dissolution)).

A possible biopharmaceutics risk assessment framework ranks the risk of a drug product from very low to very high based on the understanding of in vivo dissolution and absorption influenced by the drug product attributes including active pharmaceutical ingredient's (API's) physicochemical properties and critical bioavailability attributes (CBAs) and their interactions with the gastrointestinal physiological conditions. Levels are: very high, high, moderate, low, and very low.

Please consider reviewing the following references before completing this survey: workshop website (see above)

Lawrence Yu's recent presentation "Perspectives on the Future State of Dissolution Testing", posted at workshop website

2021 M9 Biopharmaceutics Classification System-Based Biowaivers (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m9-biopharmaceutics-classification-system-based-biowaivers>)

2018 FDA guidance on Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dissolution-testing-and-acceptance-criteria-immediate-release-solid-oral-dosage-form-drug-products>)

and 1997 FDA guidance on Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/extended-release-oral-dosage-forms-development-evaluation-and-application-vitroin-in-vivo-correlations>).

**CONSENT** In completing this research survey, you are providing consent for us to collect your survey answers. Please know that this activity involves research. Your participation is voluntary, and you can withdraw at any time. Basic eligibility criteria: Adults with an interest in promoting public standards for oral solid dosage forms (e.g. tablets and capsules) via in vitro dissolution testing.

Procedures are this written survey. This research survey will take approximately 25 minutes. The data will be stored on a password-protected computer in a locked office in a secure building. The survey is anonymous. Summary results will be shared with FDA and the public. No individual survey results will be shared with FDA or the public.

Contact information for questions or enrollment is:

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- I consent (0)
- I do not consent (1)

Type of Business (select one):

- Academia (1)
- New Drug Pharmaceutical Industry (2)
- Generic Drug Pharmaceutical Industry (3)
- Government/Regulatory Authority (4)
- Software Developer Company (6)
- Consultant (7)
- Contract Research Organization (8)
- Media/Journals (9)
- Other (16) \_\_\_\_\_

Number of employees at your organization (select one):

- 1 (2)
- 2-49 (3)
- 50-100 (4)
- 101-1,000 (5)
- 1,001-10,000 (6)
- More than 10,000 (7)

Job Category (select one):

- Executive (2)
- Director (3)
- Scientist/Researcher (4)
- Employee (Staff) (5)
- Student/Trainee (6)

What types of pharmaceutical product(s) does your organization develop? (select all that apply)

- Innovator Products (1)
- Generic Products (2)
- Biosimilars (3)
- Organization does not develop drug products (4)
- Other (16) \_\_\_\_\_

How many years of experience do you have with in vitro dissolution testing? (select one)

- 1-2 (1)
- 3-5 (2)
- 5-10 (3)
- 10-20 (4)
- >20 (6)
- I do not have experience with in vitro dissolution testing (7)

**INSTRUCTIONS:** For each of the following 13 questions, please provide your best answer based on your current understanding of biopharmaceutics risk of oral solid dosage forms (e.g. tablets and capsules), including a possible framework spanning from very high risk to very low risk. Sometimes, if you answer affirmatively, you are asked a clarifying question. You are able to skip any question.

Do you agree that a product with a very low biopharmaceutics risk does not require routine batch in vitro dissolution testing? If yes, what is an example rationale?

Assume products with **very low** biopharmaceutics risk do not require routine batch in vitro dissolution testing. **Which other products** should not require routine batch in vitro dissolution testing? Select all that apply.

Products with **very high** biopharmaceutics risk

Products with **high** biopharmaceutics risk

Products with **moderate** biopharmaceutics risk

Products with **low** biopharmaceutics risk

Do you agree that a product with very high biopharmaceutics risk needs routine in vitro dissolution testing that has been proven to be predictive of in vivo human performance?

Without any particular additional oral biopharmaceutics insights, which initial (or default) level of biopharmaceutics risk would you suggest for each of the following 10 oral solid dosage forms (very high to very low):

Extended release (ER) tablet (e.g. via HPMC matrix)

Delayed release (DR) tablet of a Biopharmaceutics Classification System (BCS) **highly soluble** drug (e.g. via enteric coating of tablet)

Delayed release (DR) tablet of a BCS **lowly soluble** drug (e.g. via enteric coating of tablet)

Amorphous solid dispersion (ASD) tablet

Immediate release (IR) tablet of BCS class 1 drug that rapidly dissolves (per BCS M9 guidance)

IR tablet of BCS class 2 drug (and not an enabled formulation such as an ASD) and where drug is **weakly acidic**

IR tablet of BCS class 2 drug (and not an enabled formulation such as an ASD) and where drug is **weakly basic**

IR tablet of BCS class 2 drug (and not an enabled formulation such as an ASD) and where drug is **neutral**

IR tablet of BCS class 3 drug that very rapidly dissolves (per BCS M9 guidance)

IR tablet of BCS class 4 drug (and not an enabled formulation such as an ASD)

For any of these 10 oral solid dosage forms, please add any additional comments or limitations about the initial (or default) level of biopharmaceutics risk that you suggest:

To the extent that best practice methods are available, briefly describe one or more best practices to assess that in vivo dissolution is not the rate-limiting step in absorption.

Do you agree that good biopharmaceutics risk understanding can mitigate and lower a product's initial (or default) biopharmaceutics risk (e.g. reduce from very high to moderate)?

What data and/or data analysis would be needed for an oral solid dosage form with an initial (or default) risk of very high to be characterized as moderate risk (or lower)?

Some marketed oral solid dosage form products with presumably very high biopharmaceutics risk do not have an in vitro-in vivo correlation (IVIVC) study, per the 1997 FDA IVIVC guidance. In your experience, **why is this the case?** Select all that apply (maximum of five selections), with 1 denoting the most common or influential reason, and 5 denoting the fifth most common or influential reason.

FDA IVIVC analysis is not required, so clinical studies are not prioritized for IVIVC studies.

FDA IVIVC analysis is not required, so further CMC effort is not prioritized for IVIVC studies.

The high failure rate of FDA level A IVIVC makes attempting IVIVC unattractive.

We expect a safe space rather than an IVIVC for most of our (very) high risk products.

We understand our products so well that attempting IVIVC is not necessary. Even successful IVIVC analysis would not add sufficiently to product understanding, at least in terms of known critical bioavailability attributes (CBAs).

IVIVC studies are too expensive.

We do not know how to conduct IVIVC testing (e.g. the guidance is unclear).

FDA IVIVC is too easy to conduct and achieve.

Using a Likert scale of 1 to 5, indicate your response to the following four statements about the 1997 FDA IVIVC guidance (1=Strongly Agree, 2=Agree, 3=Neutral, 4=Disagree, 5=Strongly Disagree):

The guidance should be withdrawn and not replaced.

The guidance should be revised.

The prediction error criteria for FDA level A IVIVC **internal** predictability are **easy** to pass.

The prediction error criteria for FDA level A IVIVC **external** predictability are **easy** to pass.

The prediction error criteria for FDA level A IVIVC **internal** predictability are **difficult** to pass.

The prediction error criteria for FDA level A IVIVC **external** predictability are **difficult** to pass.

Assume that the introduction of new and sometimes better in vitro dissolution methods (e.g. media, apparatuses) for “**brand products**” (e.g. NDA products) is inhibited by the uncertainty of global regulatory acceptance. **Which entity** is the largest (or most common) barrier? Select all that apply (maximum of five selections), with 1 denoting the largest (or most common) barrier, and 5 denoting the fifth largest (or most common) barrier.

Product sponsor

FDA

EMA

PMDA

Another national regulatory agency

United States Pharmacopeia (USP)

European Pharmacopoeia (EP)

Japanese Pharmacopoeia (JP)

Another compendial agency

Assume that the introduction of new and sometimes better in vitro dissolution methods (e.g. media, apparatuses) for “generic products” (e.g. ANDA products) is inhibited by the uncertainty of global regulatory acceptance. Which entity is the largest (or most common) barrier? Select all that apply (maximum of five selections), with 1 denoting the largest (or most common) barrier, and 5 denoting the fifth largest (or most common) barrier.

Product sponsor

FDA

EMA

PMDA

Another national regulatory agency

United States Pharmacopeia (USP)

European Pharmacopoeia (EP)

Japanese Pharmacopoeia (JP)

Another compendial agency

Do you agree that there is a potential benefit of having both a quality control method for batch release and a biopredictive/biorelevant method for biowaiver or bridging scenarios?

Assume there is allowance for both a quality control method for batch release and a biopredictive/biorelevant method for biowaiver or bridging scenarios. Under which situations (if any) do you see a potential utilization of two such methods? Select all that apply.

Very high biopharmaceutics risk

High biopharmaceutics risk

Moderate biopharmaceutics risk

Low biopharmaceutics risk

Very low biopharmaceutics risk

Thank you.