



# Pharmaceutical Packaging: Moisture Permeation and Integrity Testing

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Co-sponsored by the Product Quality Research Institute (PQRI) and USP



Package integrity is necessary to maintain a drug product's quality throughout its shelf life. Thus, packaging systems must demonstrate satisfactory container-closure integrity. Package moisture permeation is a critical quality attribute for solid oral dosage forms, with moisture uptake being a common cause for product package failures. Current permeation methods in *USP–NF* General Chapter <671> Containers—Performance Testing establish equivalence for packaging (cap/bottle and blister packs) based on the *USP–NF* standards of well-closed or tight containers. Chapter <671> is being revised to include a new permeation method for pharmaceutical manufacturers.

This workshop will provide a platform for stakeholders to discuss proposed revisions to *USP–NF* permeation and leak standards and to future chapters.

## Topics Include

- ▶ USP activities regarding the revision to current Chapter <671>
- ▶ New permeation tests for pharmaceutical manufacturers
- ▶ Current permeation test classification (well-closed or tight container) and future classification expansion
- ▶ Moisture permeation testing for high barrier vs. low barrier materials
- ▶ Desiccant choice and amount

## Who Should Participate

Stakeholders (industry, regulators, and associations) interested in furthering the science of maintaining packaging integrity for solid oral dosage forms, including professionals working in or with:

- ▶ Research and development
- ▶ Contract research organizations
- ▶ Contract manufacturing organizations
- ▶ Contract packagers and repackagers
- ▶ Packaging component manufacturing
- ▶ Packaging component suppliers
- ▶ Regulatory affairs
- ▶ Quality assurance/quality control

## REGISTRATION AND ADDITIONAL INFORMATION

Early bird and group discounts are available. Visit <http://uspgo.to/pharma-packaging-workshop>, email [conferences@usp.org](mailto:conferences@usp.org), or call +1-301-816-8136.