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*The Standard of Quality<sup>SM</sup>*

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## **USP Chapter <671> Containers – Performance Testing**

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## Revision of <671> Containers—Background

- ▶ In 2005, the Packaging and Storage Expert Committee (PSEC) reviewed chapters containing standards for qualifying plastic and glass materials used to package medicinal articles (pharmaceuticals, biologics, dietary supplement and devices)



## Issues Identified

- ◆ Chapters contained standards for material no longer used by industry.
- ◆ Standards needed for new container materials being used by industry.
- ◆ Some test methods needed updating.



## Issues identified

- ◆ New technologies could be added.
- ◆ Redundancy between chapters – difficult to locate information.
- ◆ Outdated references.



## Revision of <671> Containers—Background

- ◆ PSEC decided to revise the chapters in two phases:
  - ▶ Phase 1
    - Remove outdated standards
    - Eliminate redundancy and reorganize chapters
    - Update references and test methods
  - ▶ Phase 2
    - Incorporate new standards, methods and technologies



## Result of Review

- ◆ In 2005 the PSEC moved forward with the Phase 1 revision of <671> Containers—Permeations



## <671> Reorganization

### ◆ <671> Containers—Permeations

- ▶ Provided standards for determining moisture permeability of plastic containers used to store pharmaceuticals
- ▶ Permeation Tests for:
  - Multiple-Unit Containers for Capsules and Tablets
  - Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets



## <671> Reorganization

### The chapter was renamed <671> Containers—Performance Testing

- ◆ Provides standards for determining the functional properties of plastic and glass containers
  - ▶ Water Permeation Test—determines moisture permeability of container (water gain)
  - ▶ Water Weight Loss Test—determines moisture permeability of container
  - ▶ Light Transmission Test—determines if a container is light-resistant



## <671> Reorganization

- ◆ Water Permeation Test for Polyethylene and Polypropylene containers (*without closure*) was removed from <661> Containers and added to <671>
- ◆ Light Transmission Test was removed from <661> Containers and added to <671>



## Test Method Update

- ◆ General Chapter <661> Containers had a vapor permeation rate test (water weight loss) for Polyethylene Terephthalate (PET) and Polyethylene Terephthalate (PETG) bottles.
- ◆ At one time aqueous solutions were primarily packaged in PET or PETG bottle.
- ◆ Presently, aqueous solutions are packaged in bottles made of other polymers besides PET and PETG.



## Test Method Update

- ◆ PSEC revised the vapor permeation rate test so that it could be used to qualify any container used to package an aqueous product.
- ◆ The section was renamed Multiple-Unit Containers and Unit-Dose Containers for Liquids and was removed from <661> Containers and added to <671>.



## Test Method Update

### Multiple-Unit Containers and Unit-Dose Containers for Liquids sections:

- ◆ Provide procedures for testing unopened market containers and multiple-unit containers under conditions of use
- ◆ Testing Calculation has been changed: now calculate percent water loss per year
- ◆ Change in testing conditions:  $25 \pm 2^{\circ}$  and Relative Humidity of  $40 \pm 2\%$
- ◆ Container meets the requirement of a tight container if the average water weight loss is less than or equal to 2.5% (w/w) per year



# Outline of Current <671> Containers— Performance Testing

- ◆ Introduction
- ◆ Permeation Tests
  - ▶ Multiple-Unit Containers for Capsules and Tablets
  - ▶ Multiple-Unit Containers for Capsules and Tablets (without closure)
  - ▶ Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets
  - ▶ Multiple-Unit Containers and Unit-Dose Containers for Liquids
- ◆ Light Transmission Test



## Conclusions

- ◆ Standards no longer needed were eliminated
- ◆ Standards for new container materials were added.
- ◆ Test methods were updated as appropriate.
- ◆ The chapter was reorganized for clarity and elimination of redundancies and outdated material.



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*Thank You*