

# Connected at Every Level Compliance

## Packaging Systems and Desiccants

### Are you ready for the changes to USP <661> Plastic packaging systems and <670> Packaging components?

The U.S. Pharmacopeia (USP) revised its characterization analysis for plastic packaging systems and the auxiliary packaging components monograph effective May 01, 2016. The revised USP monographs were updated to better identify means of ensuring that the primary packaging system is suited for its intended use.

The revised USP <661> will significantly improve the characterization of the packaging material by establishing its:

- Identity
- Biocompatibility (Biological Reactivity)
- General Physicochemical properties
- Additives
- Extractable metals

The revised USP <670> was updated to include the evaluation of all desiccants within the packaging system. The following new tests are now required on all desiccants:

- Appearance
- Identification
- Inorganic Impurities
- Specific tests like pH and loss of drying
- Moisture Adsorption capacity

These revisions are already in affect and are required for all new drug applications.

### The Alcami Advantage What does this mean for you?

A thorough evaluation of the chosen packaging system and its components is now required to ensure compatibility with the pharmaceutical product and that all materials are safe for use.

Alcami has the required equipment and a team of experts well versed in extractable / leachable studies available to help you address the new requirements for packaging materials in compliance with USP <1663> and <1664> as well as the new desiccant testing as directed in USP <670> Auxiliary Packaging Components.

Let Alcami guide you through these regulatory changes based on our vast experience across multiple materials and programs. Our experts can determine what is needed to assure your compliance and turn this into an action plan that we have resources ready to execute.

At Alcami, we are committed to helping you achieve World Class regulatory compliance. Connect with one of our experts to ensure the best possible outcome for your product at every level.

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