Excipients Reference Standards

Background

In medicines, excipients include everything except the active pharmaceutical ingredients (APIs). Despite being called “inactive” ingredients, they play a critical role in drug development, delivery, effectiveness, and stability. They comprise up to 90% of medications and serve important functions, including as binders, disintegrants, coatings, preservatives, colors, and flavorings.

Opportunity to strengthen quality

Excipients are sourced from suppliers around the world. Manufacturers and regulators must confirm the consistent quality of drug ingredients, including excipients, regardless of where they come from. More specifically, they must verify that an excipient is safe in the amount it will be used, performs its intended function in the product, does not adversely affect the bioavailability and performance of the active drug, and is manufactured according to good manufacturing practices.

USP solutions

- The *United States Pharmacopeia–National Formulary* (*USP–NF*) includes documentary standards that provide validated test procedures to establish the identity, purity, and quality of excipients.
- USP Reference Standards for excipients have been tested and approved as suitable for use as comparison standards in *USP–NF* tests and assays.
- USP Education offers on-demand learning opportunities to help laboratory staff use USP Excipients Reference Standards as intended.

Why it’s important

Excipients are essential for delivering a medicine’s active pharmaceutical ingredient(s) and affect how well a drug functions in the body. They play a crucial role in the pharmaceutical industry, streamlining the processing of the drug delivery system during manufacturing, boosting the effectiveness and/or delivery of the drug, and helping to maintain the integrity of the drug during storage. Choosing the correct excipient can reduce manufacturing costs.

USP standards for excipients help manufacturers and regulators verify the identity, strength, purity, and performance of excipients used in medicines, increasing the availability of quality medicines and building confidence that medicines will perform as expected.

Web resources

- https://www.usp.org/excipients
- https://store.usp.org/home
- https://uspharmacopeia.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67