Small molecule Reference Standards

Background

Low molecular weight, small molecule drugs have been the mainstay of the pharmaceutical industry for nearly a century. Manufactured by chemical synthesis, small molecule drug method development and analysis includes medicinal chemistry, metabolite identification, impurity profiling, drug metabolism, and pharmacokinetics.

The development, manufacture, distribution, and administration of small molecule drugs involves a complex, global supply chain that requires quality checks throughout. With multiple manufacturers around the world, a common understanding of quality is important to ensure consistency and protect patients.

Opportunity to strengthen quality

Successful testing and release of small molecule drugs requires efficient analytical tools, validation guidelines, and practices. USP's independently vetted, science-based Reference Standards enable manufacturers and regulators to confirm the consistent quality of medicines, regardless of where they are made.

USP solutions

The *United States Pharmacopeia–National Formulary* (*USP–NF*) includes documentary standards for small molecule drugs. These standards articulate quality expectations and describe test(s) to validate that a small molecule drug meets the specified acceptance criteria.

USP Reference Standards are highly characterized physical specimens of ingredients and finished products used in conjunction with USP documentary standards to verify that a medicine and its ingredients pass analytical tests and meet quality requirements.

Therapeutic areas:

Anesthetics	**Antivirals**	**Hepatic**	**Psychiatrics**
Analgesics	**Cardiovascular**	**Immuno-suppressants**	**Psychoactives**
Antibiotics	**Cough & Cold**	**Insecticides**	**Pulmonary**
Anticoagulants & Antiplatelets	**Dental**	**Muscle Relaxants**	**Radiopharmaceuticals**
Antidotes & Chelators	**Dermatology**	**Nonradioactive Imaging Agents**	**Renal**
Antihistamines	**Disintegrants**	**Oncology**	**Steroids**
Anti-hyperlipidemics	**Diuretics**	**Ophthalmology**	**Veterinary**
Antimicrobials	**Endocrine**	**Opioids**	
Antiseptics	**Gastro-intestinal**	**Others-Chemical Medicines**	

Why it's important

USP standards are used in product development, quality assurance, and quality control activities around the world. Manufacturers are required by law to ensure that their products meet USP standards to be marketed in the U.S. In addition, government regulators in more than 50 countries rely on USP standards to help ensure medicine quality. This broad acceptance of USP standards enables consistency in manufacturing and product quality. Because USP standards provide precise quality specifications, they help make the approval process for generic medicines more efficient, thereby improving patient access to essential medicines that they can trust.

Web resources

- https://www.usp.org/chemical-medicines
- https://www.usp.org/reference-standards/reference-standards-catalog
- https://store.usp.org/home