USP Reference Standards

Background

More than 131 million Americans – 66 percent of adults – use prescription drugs. In 2020, the domestic pharmaceutical market was valued at $425 billion. Prescription medicines and their ingredients are manufactured in facilities all over the world. Manufacturers and regulators conduct extensive quality testing to help safeguard the quality of the medicines that reach consumers.

Opportunity to strengthen quality

To verify the accuracy of analytical testing results, manufacturers and regulatory authorities analyze a material of known composition along with the test samples. Manufacturers and regulators need reliable sources of highly purified and characterized control samples of drug ingredients and finished drug products to be confident in the results of their quality testing procedures.

USP solutions

USP offers over 7,000 USP Reference Standards, highly characterized physical specimens of drug substances, excipients, food ingredients, impurities, degradation products, dietary supplements, compendial reagents, and performance calibrators. They are used primarily for quality control in conducting the assays and tests in USP documentary standards.

Only USP Reference Standards are linked to official USP monographs that definitively describe specifications for evaluating a medicine's identity, purity, potency, and performance. When monograph tests or assays require the use of a USP Reference Standard, only those test results obtained using the specified USP Reference Standard are conclusive.

Why it's important

USP standards play an important role in the global medicines supply chain, helping governments and manufacturers increase the availability of safe, quality medicines and building patient and healthcare provider trust. Comparing test results obtained with product samples against results obtained when a USP Reference Standard is tested enables manufacturers to verify their products' identity, purity, strength, and performance. Regulators worldwide use USP standards to verify the consistency and quality of drug ingredients and products so that patients can trust their medicines will work as expected no matter who manufactures them or where they are made.

Web resources

- https://www.usp.org/reference-standards
- https://store.usp.org/all-reference-standards/category/USP-1010
- https://www.usp.org/reference-standards/reference-standards-catalog