The Role of a Public Drug Quality Standard

A public standard is a benchmark that consists of tests and other measures to determine a drug's identity, purity, quality, potency, and consistency. Public standards establish the parameters by which it can be determined that a drug meets key quality attributes regardless of the manufacturer or manufacturing process. They are utilized by manufacturers and provide protection to patients throughout a product's lifecycle from development to the patient. Unlike the private specifications developed by industry, public standards are available to anyone to use to test quality at any point in the supply chain. This is increasingly important in today's global pharmaceutical marketplace, where the majority of drugs consumed in the U.S. come from outside the country.

USP standards developed with input from Council of Experts comprising 1000 representatives from industry, academe, regulatory science, healthcare practice and other areas from multiple scientific disciplines

USP standards vetted through an open comment process, in which stakeholder and public input is key

Private standard developed with input from sole manufacturer

PUBLIC STANDARD	PRIVATE SPECIFICATIONS
Developed by standards-setting organization	Developed by individual company or the regulator
Publicly available	Known only to the manufacturer and regulator
Can be used by any company or regulator	Can only be used by regulator and company that developed it
Supports multiple products on market	Applies to single product on the market
Establishes a single benchmark for quality and consistency regardless of manufacturer or manufacturing process	Establishes a single specification that will vary from one manufacturer to another.
Allows for input from multiple stakeholders during its development	Based on proprietary knowledge and information
Developed using a transparent, collaborative process	Details of its development are undisclosed
Encourages multiple entrants into the market	Encourages single entry into market
Can serve as a product development tool that facilitates procedures and product development for subsequent entry products	Applies only to the product for which it was developed
Once developed, is dynamic and continuously open for revision as science and the market evolve	Once developed, remains relatively static
During product recalls/removal from the market, remains available for use and can facilitate product development and access	During product recalls/removal from the market, is not available to any other manufacturer or other independent testing agencies