

Week 5 Assignment: Need or lack of Need for USP Reference Standard.

In order to determine whether or not there is a need for the United States Pharmacopeia Convention (USP), we should first understand what it is the USP and what it does.

The USP is an independent non-profit scientific organization whose focus is building the trust in the supply of safe, quality medicines. Founded in 1820 in Washington, D.C., it develops and disseminates public compendial quality standards for medicines. Their mission is the improvement of global health through public standards and related programs. The USP's primary compendia of standards are the United States Pharmacopeia and the National Formulary (USP-NF). Even though their standards may be adapted or adopted by organizations or governments worldwide, they have no role in enforcement. Enforcement is the role of the Food and Drug Administration and other government authorities in the United States and elsewhere.¹

The USP establishes written and physical standards for medicines food ingredients and dietary supplement. These standard articles are recognized in the USP National Formulary. They have general notices that are exclusively devoted to labeling. The articles in the compendia are subject to compliance with labeling requirements that are expressed by government bodies. Drugs and biologics recognized in the USP must comply with standards for strength, quality, and purity unless it is labeled to show all respects in which the drug differs. They also provide to the public the information of the official documentary standards for pharmaceutical ingredients in the *USP-NF* that link directly with our primary reference standards.²

What is the USP reference standard? The pharmaceutical reference standard is a highly characterized material that is suitable to test the identity, strength, quality, and purity of substances for medicinal products and products for pharmaceutical use. The reference standards are rigorously tested and evaluated by multiple independent laboratories including USP, commercial, regulatory, and academic labs.³

One could question why we would need reference standards for food and drugs. The answer to that question would be for the safety of the consumer. Speaking only about cannabis for now, there is a need to have these standards in place to protect patients. There are multiple factors that could come to play when it comes to how harmful cannabis can be to consumers if there weren't any rigorous testing involved. For instance, the soil in which the plant is grown may contain substances that could be toxic if consumed. The machinery that is used in manufacturing could carry harmful contaminants. What about the plant itself? What does each cannabinoid do? When providers recommend cannabis to their patients, what should they recommend and how much? Knowing if a cannabinoid is volatile or non-volatile which would determine how it is stored or how workers should handle it.

A cannabis expert panel has recommended that the USP develop reference standards for quantitative measurement of multiple cannabinoids such as, Delta 9, Delta 8, THCA, CBD, CBDA, CBG, CBGA, CBC, CBDVA, CBDV, THCV, THCVa and CBN (Other cannabinoids may be added in the future as research continues). These reference standards would be key in protecting the public if they are adapted by the government and companies.³

To answer the question of whether or not there is a need for USP reference standards, in my opinion the answer is yes. Consumers should know about the drugs that they are taking, and protocols should be in place to ensure safety.

References

¹FAQs: USP and its standards. USP. <https://www.usp.org/frequently-asked-questions/usp-and-its-standards>. Accessed November 23, 2021.

²Contributors: Will Whitaker, Will Whitaker, Michael Levy. What is the U.S. pharmacopeia? What is the U.S. Pharmacopeia? | Quality Matters | U.S. Pharmacopeia Blog. <https://qualitymatters.usp.org/what-us-pharmacopeia>. Accessed November 23, 2021.

³MCST 609 Advanced Cannabinoid Chemistry and Analytic Testing Methodology. lecture presented at the: University of Maryland Online