



The Global Health Standards Program

A USP Commitment to Public Health Globally



Introduction

USP estimates that a significant proportion of medicines on the World Health Organization's (WHO) Model List of Essential Medicines lack quality public monographs and standards. To address high burden health challenges, the United States Pharmacopeial Convention (USP) has established the Global Health Standards program, dedicated to developing monographs and reference standards for these lifesaving medicines.

Purpose

The objectives of the Global Health Standards program are to:

- Ensure availability of relevant, modern standards for the world's most essential medicines;
- Enable accessibility of these standards globally; and
- Engage stakeholders for development, adoption, and implementation of these standards for improved public health outcomes

USP's global help monographs are official USP monographs for articles which are not currently legally marketed in the United States, but which have been approved by a stringent regulatory authority and are used for essential purposes in other parts of the world. Widespread adoption and use of these standards will help governments, regulators, and manufacturers increase the availability and accessibility of quality-assured essential medicines in support of achieving Universal Health Coverage.

FOR MORE INFORMATION

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Process

The development of these monographs uses the same collaborative and transparent USP monograph development processes, including proposal in *PF*, expert committee review and approval. Selection and prioritization of new monographs is determined by an Advisory Group comprising of experts/ stakeholders in the global health community to ensure these are relevant, modern standards for the world's most essential medicines.

Through the Global Health Standards program, USP is addressing this gap and thus fulfilling its mission to improve global health through public standards that help ensure the quality, safety, and benefit of medicines.

Why Standards Matter

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 manufacturing process or origin. Standards provide protection to patients throughout a product's lifecycle, from development to delivery, by ensuring consistent composition of the product.

Upcoming Monographs for Development