

Glossary

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts.

Chemical reference substance

The term *chemical reference substance*, as used in this text, refers to an authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use.

Primary chemical reference substance

A designated primary chemical reference substance is one that is widely acknowledged to have the appropriate qualities within a specified context, and whose assigned content when used as an assay standard is accepted without requiring comparison with another chemical substance.

Secondary chemical reference substance

A secondary chemical reference substance is a substance whose characteristics are assigned and/or calibrated by comparison with a primary chemical reference substance. The extent of characterization and testing of a secondary chemical reference substance may be less than for a primary chemical reference substance. Although this definition may apply *inter alia* to some substances termed “working standards”, part B of these guidelines is intended to apply to secondary reference substances supplied as “official”, e.g. regional/national standards, and not to manufacturers’ or other laboratories’ working standards.

International Chemical Reference Substance

International Chemical Reference Substances (ICRS) are primary chemical reference substances established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied primarily for use in physical and chemical tests and assays described in the specifications for quality control of drugs published in *The International Pharmacopoeia* or proposed in draft monographs. The ICRS may be used to calibrate secondary standards.

Pharmacopoeial reference standards

The specificity of pharmacopoeial reference substances has been addressed in the introduction of *ISO Guide: General requirements for the competence of reference material producers*. “Pharmacopoeial standards and substances are established and distributed by pharmacopoeial authorities following the general principles of this Guide. It should be noted, however, that a different approach is used by the pharmacopoeial authorities to give the user the information provided by certificate of analysis and expiration dates” (9).