

GLOSSARY

Acceptance criteria—Acceptance criteria are numerical limits, ranges, or other characterization for the tests described. They establish the standards to which a drug substance or drug product should conform to be considered acceptable for its intended use.

Assay test—The Assay test procedures determine the content of an active ingredient in a drug substance or a drug product.

Bioidentity test—The Bioidentity test is a biological activity procedure that is designed to ensure that a biologics and biotechnology active ingredient has a defined biological activity of a given magnitude or within a given range.

Biological Activity—The biological activity is the specific ability or capacity of a drug substance or product to achieve a defined biological effect. Potency is the quantitative measure of the biological activity.

Botanical—Botanicals are plant materials that claim to affect the well-being of an individual.

Certificate of Analysis (COA)—A Certificate of Analysis is a list of the analytical tests, acceptance criteria, and results obtained on a particular article.

Council of Experts—USP's standards-setting body, the Council of Experts, is composed of scientific experts elected by the USP Convention for their expertise and leadership. These elected members serve as chairs of individual Expert Committees.

Definition—The Definition section of a monograph includes functional properties, chemical composition, and, when needed for a biological/ biotechnological substance, performance characteristics. When a manufacturer relies upon techniques to assess these performance characteristics that might require disclosure of proprietary information, the name of the general technique [e.g., Enzyme-Linked Immunosorbent Assay (ELISA)] and its acceptance criteria should be provided in the Definition. For biotechnology-derived substances, the Definition should include a statement on limits for host cell DNA and host cell protein impurities. These limits are process-specific, and quantitative procedures are not included in monographs. The Definition indicates the acceptance criteria for the assay, reflective of content/purity, with exceptions as needed.

Degradants—Degradants are products of the degradation of an active ingredient that cause a loss of potency over the life of a product.

Desired biological product—Desired biological products include (1) A protein, carbohydrate, or lipid, which has the expected structure or (2) a protein that is expected from the DNA sequence and anticipated post-translational modification, including

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isoforms and glycoforms, and from the intended downstream modification, to produce an active biological molecule.

Drug product (Dosage form; Finished product)—A drug product contains one or more drug substances (active pharmaceutical ingredients), usually with excipients.

Drug substance (Active pharmaceutical ingredient)—A drug substance is the material that subsequently is used to formulate, usually with excipients, the drug product. It can be composed of the desired material, product-related substances, and product—or process-related impurities. It also may contain other components, including buffers. This often is referred to as bulk concentrate, bulk intermediate, or simply bulk by the biologics and biotechnology industry.

Essential minor component—An essential minor component is any material present in an excipient that is not the main chemical component or components, and is necessary for the excipient's proper performance during use.

Excipients—Excipients are those components of a finished medicinal drug product other than the active pharmaceutical ingredient (API). They are included in the formulation to facilitate manufacture, enhance stability, control release of API from the product, assist in product identification, or enhance other product characteristics.

Expert Committee—An Expert Committee is a group of individual experts elected by the Council of Experts for their knowledge and experience in specific areas of interest. Each Expert Committee is chaired by a member of the Council of Experts.

General Chapter—A General Chapter describes, explains, and elaborates upon a principle, test, procedure, or concept having relevance to compendial standards.

Impurity—An impurity is any component present in the excipient, drug substance, or drug product that is not the desired product, a product-related substance, or excipient, including buffer components. It may be either process- or product-related.

Label—The label is the document physically attached directly to the packaging materials that are in direct contact with the excipient, drug substance, or drug product.

Labeling—Labeling includes the label and the documents included with, but not attached to, the packaging materials that are in direct contact with the excipient, drug substance, or preparation (e.g., package insert).

Moiety—The term moiety generally is used to signify part of a molecule, e.g., in an ester R^1COOR^2 the alcohol moiety is R^2O . The term should not be used for a small fragment of a molecule. In pharmaceuticals, the active moiety would be the portion of the molecule that is responsible for the therapeutic effect.

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Monograph—The monograph contains the requirements and specifications that must be met to claim compendial compliance for a drug substance, drug product, botanical, vaccine, excipient, medical gas, or medical device.

Pharmacopeial Forum (PF)—*PF* is USP's bimonthly journal of standards development and official compendial revisions. This publication contains all proposed revisions to the *USP-NF* prior to their official adoption.

Polydispersed substances—Polydispersed substances are polymers with varying chain lengths and molecular weights, but having the same monomeric units.

Potency—As applied to the biologics and biotech areas, this is the measure of the biological activity using a suitable quantitative biological assay (also called potency assay or bioassay), based upon the product's attribute, which is linked to the relevant biological properties.

Procedure—A procedure is the description of how a test is conducted, including the appropriate descriptions, etc., of the instruments, solutions, and reactions to be carried out, as well as the order of the different steps.

Process-related impurities—As applied to the biologics and biotechnology areas, these are impurities derived from the manufacturing process. They may be derived from source tissue or host cells (e.g., protein, DNA), cell culture (e.g., inducers, antibiotics, or media components), or downstream processing (e.g., processing reagents or column leachables).

Product-related impurities—As applied to the biologics and biotechnology areas, these are molecular variants of the desired product (e.g., precursors, certain degradation products arising during manufacture and/or storage), which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety.

Product-related substances—As applied to the biologics and biotechnology areas, these are molecular variants of the desired product formed during manufacture and/or storage, which are active and have no deleterious effect on the safety and efficacy of the drug substance/drug product. These variants possess properties comparable to the desired product and are not considered impurities.

Reporting threshold—The reporting threshold is the level below which impurities need not be quantified or added to total impurity levels.

Request for Revision—A Request for Revision is a proposal to revise the *USP-NF*.

Revision—A revision is a change to the official text of the *USP-NF*.

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Revision process—The revision process is the series of actions required to effect a revision to the *USP–NF*, as set forth in the Rules and Procedures of the 2005-2010 Council of Experts.

Scientific Liaison—The USP Scientific Liaison is the individual who serves as a point of contact between the Expert Committees and Sponsors or others in the pharmaceutical industry.

Specific tests—Specific tests are those generally included in a specification to control a process or formulation specific property.

Specification—A specification is a list of tests, references to analytical procedures, and appropriate acceptance criteria. It establishes the set of criteria to which an excipient, drug substance, or drug product should conform to be considered acceptable for its intended use. “Conformance to specification” means that the excipient, drug substance, and drug product, when tested according to the listed analytical procedures, will meet the acceptance criteria.

Sponsor – The submitter of a Request for Revision.

Stability indicating—A procedure(s) that is stability indicating is one that can accurately and precisely quantify the decrease of the active pharmaceutical ingredient content, alone or in the drug product, due to degradation.

Standard—The Standard includes the contents of a monograph, including definition, description, package, storage, and labeling requirements, its specification, and Reference Standards, if needed.

Technology transfer—Technology transfer is the process of transferring a technical specification from one site to another.

Test—A test assesses a product attribute by a procedure.

Universal tests—Universal tests include Description, Identification, Impurity(s), and Assay. With few exceptions, all monographs should include these tests.