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StandardTerminology Relating to Process Analytical Technology in the Pharmaceutical Industry[1]

This standard is issued under the fixed designation E2363; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This terminology covers process analytical technology in the pharmaceutical industry. Terms are defined as they are used relative to the PAT framework in the pharmaceutical industry. Terms that are generally understood and in common usage or adequately defined in other readily available references are not included except where particular delineation to process analytical technology may be more clearly stated.

1.2 This terminology is therefore intended to be selective of terms used generally in process analytical technology as it is applied in the pharmaceutical industry and published in a number of documents, such as those listed in the succeeding sections. The listing is also intended to define terms that appear prominently within other related ASTM standards and do not appear elsewhere.

1.3 The definitions are substantially identical to those published by the U.S. Food and Drug Administration and other authoritative bodies, such as ISO, IEC, ITU, and national standards organizations.

1.4 This terminology supplements current documents on terminology that concentrate on process analytical technology as it is applied in the pharmaceutical industry.

1.5 An increasing number of product designations and designations for chemical, physical, mechanical, analytical, and statistical tests and standards are coming into common usage in the literature, regulatory environment, and commerce associated with process analytical technology in the pharmaceutical industry. Section 2 lists those documents referenced in this terminology.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E456 Terminology Relating to Quality and Statistics

2.2 *U.S. Government Publications:*

21 CFR 210.3(b) Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General—Definitions[3]

21 CFR 314.3(b) Applications for FDA Approval to Market a New Drug—General Provisions—Definitions[3]

FDA/ICH Q7A Guidance Document GMP Guidance for APIs and Its Use During Inspections[4]

FDA/ICH Q9 Guidance for Industry—Quality Risk Management[4]

U.S. FDA PAT Guidance Document Guidance for Industry PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance[4]

2.3 *Other Publication:*

ISO EN 14971 Medical Devices—Application of Risk Management for Medical Devices[5]

3. Terminology

3.1 *Definitions:*

acceptance criteria, *n*—numerical limits, ranges, process signatures, or other suitable measures that are necessary for making a decision to accept or reject the result of a process, in-process variable, a product or any other convenient subgroups of manufactured units.

[1] This terminology is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical Products and is the direct responsibility of Subcommittee E55.91 on Terminology.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[4] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

analyzer, *n*—an instrument designed to measure and report a property of the process, material, or environmental condition.

at-line measurements, *n*—measurement where the sample is removed, isolated from, and analyzed in close proximity to the process stream.

attribute, *n*—a characteristic or inherent property or feature.

batch, *n*—a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. **21 CFR 210.3(b)**

batch number, *n*—a combination of numbers, letters, and/or symbols that uniquely identifies a batch and from which the production and distribution history can be determined.

batch process, *n*—a noncontinuous operation in which discrete quantities of material are transformed using individual or sequential steps. **21 CFR 210.3(b)**

computer system, *n*—a group of hardware components and associated software designed and assembled to perform a specific function or group of functions. **FDA/ICH Q7A Guidance Document**

contamination, *n*—the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, API (active pharmaceutical ingredient), or dosage form during production, sampling, packaging, or repackaging, storage, or transport. **FDA/ICH Q7A Guidance Document**

contract manufacturer, *n*—a manufacturer who performs some aspect of manufacturing on behalf of another entity.

continuous process, *n*—a process in which material is added, processed, and removed in an uninterrupted manner.

cross-contamination, *n*—contamination of a material or product with another material or product. **FDA/ICH Q7A Guidance Document**

Design of Experiments (DoE), *n*—the arrangement in which an experimental program is to be conducted, and the selection of the levels (versions) of one or more factors or factor combinations to be included in the experiment. **E456**

deviation, *n*—departure from an approved instruction or established standard. **FDA/ICH Q7A Guidance Document**

drug product, *n*—a drug product is a finished dosage form (for example, tablets, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. **21 CFR 314.3(b)**

impurity, *n*—any component present in a raw material, intermediate, API, or dosage form that is not the desired entity.

impurity profile, *n*—a description of the identified and unidentified impurities present in a raw material, intermediate, API, or dosage form.

in-line measurements, *n*—measurement where the sample is not removed from the process stream, and can be invasive or non-invasive.

in-process material, *n*—any material(s) fabricated, compounded, blended, or synthesized using a chemical, physical, or biological process that is produced for and being used in the preparation of an intermediate, drug substance, or drug product.

in-process tests, *n*—measurements performed during manufacturing and pertaining to the process or products within the process.

intermediate, *n*—material produced during manufacture that undergoes further change or purification. Intermediates may or may not be isolated.

lot number, *n*—see **batch number**.

manufacture, *n*—all operations of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage, and distribution of APIs or drug products and related controls. **FDA/ICH Q7A Guidance Document**

manufacturing process, *n*—a set of activities or operations performed to deliver a desired output.

material, *n*—a general term used to denote raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs, and packaging and labeling materials. **FDA/ICH Q7A Guidance Document**

material specification, *n*—a set of criteria to which a material must conform to be considered acceptable for its intended use.

mother liquor, *n*—the residual liquid that remains after the crystallization or isolation processes.

DISCUSSION—A mother liquor may contain unreacted materials, intermediates, API, and/or impurities. It can be used for further processing.

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off-line measurements, *n*—measurement where the sample is removed, isolated from, and analyzed in an area remote from the manufacturing process.

on-line measurements, *n*—measurement where the sample is diverted from the manufacturing process, and may be returned to the process stream.

packaging material, *n*—any material intended to contain and protect a raw material, intermediate, API, or product during storage and transport.

parameter, *n*—a measurable or quantifiable characteristic of a system or process.

parametric release, *n*—a system of release that gives assurance that the product is of the intended quality based on the information collected during the manufacturing process.

procedure, *n*—a documented description of the operations to be performed, the precautions to be taken, and the measures